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| 09/662,052 | 09/15/2000 | Vandana Yajnik | 5986/1G098-US1 | 4993 |

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Darby & Darby PC
805 Third Avenue
New York, NY 10022

EXAMINER

SOUAYA, JEHANNE E

| ART UNIT | PAPER NUMBER |
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1655

DATE MAILED: 12/10/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/662,052

Applicant(s)
Yajnik et al

Examiner
Jehanne Souaya

Art Unit
1655



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 15, 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other:

Art Unit: 1655

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-8 and 10, drawn to a nucleic acid that encode a functional NRIF3 nuclear hormone receptor co-activator, and to vectors and host cells comprising the nucleic acid, classified in class 536, subclass 23.1; class 435, subclass 320.1; and class 435, subclass 325.
 - II. Claims 11-12, drawn to an isolated NRIF3 nuclear hormone receptor co-activator, classified in class 530, subclass 350.
 - III. Claims 13-14, drawn to antibodies that bind NRIF3, classified in class 530, subclass 387.1.
 - IV. Claim 9, drawn to a method of producing NRIF3 comprising culturing a cell comprising a vector comprising an NRIF3 nucleic acid under conditions to express NRIF3, classified in class 435, subclass 71.1.
 - V. Claims 15-18, drawn to a test system comprising a cell that expresses a thyroid hormone receptor or a retinoid X receptor and a method of identifying a compound that modulates thyroid hormone receptor or retinoid X receptor, classified in class 435, subclasses 325 and 6 respectively.

Art Unit: 1655

VI. Claims 19-20, drawn to a method for identifying a compound that modulates NRIF3 interaction with nuclear hormone receptor, classified in class 435, subclass 7.31.

2. The inventions are distinct, each from the other because of the following reasons:

The inventions of groups I-III are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acid of group I is composed of deoxyribonucleotides linked by phosphodiester bonds and assumes the form of a double helix. The polypeptide of group II is composed of amino acids linked by peptide bonds and can assume complex tertiary structures. While the antibody of group III is also composed of amino acids linked by peptide bonds, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associate via disulfide bonds into a Y-shaped symmetric dimer. The products of groups I-III can be used in materially different processes, for example the DNA of group I can be used in hybridization assays, the antibody of group III can be used in immunoassays, and the polypeptide of group II can be used to make a fusion protein with an enzymatic function. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of groups I-III are patentably distinct from each other.

The invention of group I and groups IV & V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

Art Unit: 1655

product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of group I can be used to design probes and primers for the detection of NRIF3 which is materially different and requires different reagents, reaction conditions, and reaction parameters from the method for producing NRIF3 of group IV or the test system and method of identifying a compound that modulates thyroid hormone receptor or retinoid X receptor of group V.

The inventions of group I and group VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the nucleic acid of group I is not capable of use with the method for identifying a compound that modulates NRIF3 interaction with nuclear hormone receptor of group VI.

The inventions of group II and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptide of group II can be made synthetically, using known polypeptide synthesizing techniques.

The inventions of group II and groups V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

Art Unit: 1655

product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of group II can be used to make fusion proteins with enzymatic function.

The inventions of group III and groups IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the antibodies of group III are not capable of use with either the method of producing NRIF3 of group IV the test system of method of identifying a compound that modulated thyroid hormone or retinoid X receptors of group V. The different inventions have different modes of operation, different functions, and different effects.

The inventions of group III and group VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of group VI can be practiced with a materially different product than the antibody of group III, further, the antibody of group III can be used in immunoassays.

The inventions of groups IV, V, and VI are patentably distinct from each other. The method of producing the polypeptide of group IV, the method of identifying a compound that modulates thyroid hormone receptor and the test system of group V, and the method of

Art Unit: 1655

identifying a compound that modulates NRIF3 of group VI require different reagents, reaction parameters, and reaction conditions. Further, these methods are unobvious over one another.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II-VI, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. A telephone call was made to Paul F. Fehlner on November 28, 2001 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

Art Unit: 1655

amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Due to recent problems with the delivery and receipt of mail at the USPTO, applicant is advised to send a response to this restriction requirement, via facsimile, if possible. The fax phone number for this Group is (703) 305-3014.

Jehanne Souaya

Jehanne Souaya
Patent examiner
Art Unit 1655

Dec. 7, 2001